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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,652	08/05/2002	Per-Ake Nygren	2039.003	4666

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Wiggin & Dana
Intellectual Property Law Section
Docket Coordinator
One Century Tower
New Haven, CT 06508-1832

EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,652

Applicant(s)

NYGREN ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13,17-21,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13,17-21,24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed June 6, 2005 has been received and entered.

Claims 14-16, 22-23 and 26 have been cancelled. Accordingly, claims 1-13, 17-21, and 25 are pending in the instant application.

Claim Rejections - 35 USC § 101

1. The rejection of claims 20-21 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 112

2. The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "functionally equivalent" is withdrawn in view of Applicants amendment.
3. The rejection of claim 11, 13 and 19 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the use of the phrase "derived" is withdrawn in view of Applicants amendment.
4. The rejection of claims 20-21 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "substantially the same" is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 1-13, 17-19, and 24-25 under 35 U.S.C. 102(b) as being anticipated by Nord et al is maintained.

Applicants are asserting that Nord does not teach or suggest a self-assembled biomolecular structure comprising affinity modules having at least two affinity domains which may be the same or different, nor does Nord et al disclose the presently claimed feature of “specific and exclusive affinity for an affinity domain within another affinity molecule.”

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that Nord does not teach or suggest a self-assembled biomolecular structure comprising affinity modules having at least two affinity domains which may be the same or different. However, Nord et al set forth that “the Z domain is able to fold in the cytoplasm.” (See page 775). This spontaneous folding occurred with no external force, as such it meets the instantly filed limitation of “self-assembled.” Furthermore, Nord et al set forth that “repertoires of Z domain genes were assembled

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and inserted...” (See abstract). This clearly addresses the limitation of “at least two” affinity modules.

Finally, Applicants assert that Nord et al do not disclose the presently claimed feature of “specific and exclusive affinity for an affinity domain within another affinity molecule.” However, Applicants are directed to their specification, which sets forth that “specific and exclusive affinity” ***does not imply that a given affinity domain could only ever interact with a single molecular species***, rather, within the system each affinity domain has a clearly identifiable affinity partner with which it interacts much more strongly than any other domain present. (Emphasis added, Page 6 of specification). Accordingly, the breadth of the claims allows for binding with other affinity molecules. Given that the affinity molecules disclosed by Nord et al do have a clearly identifiable affinity partner, the disclosure of Nord et al is deemed to anticipate the instantly filed claim limitations.

The claims are directed to a self-assembled biomolecular structure comprising affinity modules, said affinity modules each having at least two affinity domains which may be the same or different, at least one affinity domain within each affinity module having specific and exclusive affinity for an affinity domain within another affinity module, said affinity modules being capable of biospecific interaction to form an assembled structure.

Nord et al (Nature Biotechnology Vol. 15, August 1997, pp 772-777) disclose of small protein domains, capable of specific binding to different target proteins, called

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affibodies, fused to bacterial receptor domain Z, derived from Staphylococcal protein A.

Nord et al further disclose that the Z-domain is able to spontaneously fold in the cytoplasm. Nord et al further disclose of affinity domains which have been selected from a molecular library. (See abstract and pages 775, 776).

It is noted that Nord et al do not disclose of the use of this structure for therapy (claim 25). However, this recitation is merely an intended use of the structure and therefore carries no patentable weight.

5. The rejection of Claims 20-21 under 35 U.S.C. 102(b) as being anticipated by Nilsson et al is maintained.

Applicants have amended the claims to recite "variants having modified domains wherein said modified domains have at least 80% of the binding affinity of SEQ ID NO: 2 or 3 for SPA.

Since the Patent office does not have the facilities for examining and comparing Applicants product with the product of the prior art reference, the burden is on Applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Accordingly, since the molecules disclosed by Nilsson et al are clearly variants of the claimed proteins, it is Applicants burden to show that the prior art proteins do not exhibit 80% binding compared to the instantly disclosed SEQ ID NO: 2 and 3 of the instant invention. Consequently, this rejection is maintained for reasons of record.

Nilsson et al (WO 95/19374) disclose of Z protein variant 22 and Z protein variant 17 which have 76.7 and 78.3 percent identity to SEQ ID NO: 2 and 3 of the instant invention, respectively. (See Figure 14).

Given that Nilsson et al disclose of proteins with high levels of homology, they are deemed to anticipate the claim language which recites "variants" of SEQ ID NO: 2 and 3.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 112

6. Claims 20-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 20-21 recite a protein variant having at least 80% of the binding affinity of SEQ ID NO: 2/3 for SPA.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a

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“80% binding affinity” alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed.” The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.”

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a **representative number of molecules**, usually defined by a sequence, falling within the scope of the claimed genus. At section B(1), the court states that “An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish

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or plan for obtaining the claimed chemical invention.”

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 “Written Description” Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
August 18, 2005